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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference deslor_101	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IN 2003/000156	International filing date (day/month/year) 16 April 2003 (16.04.2003)	Priority Date (day/month/year) 15 April 2002 (15.04.2002)
International Patent Classification (IPC) or national classification and IPC IPC ⁷ : C07D 401/04, A61K 31/435		
Applicant SUN PHARMACEUTICAL INDUSTRIES LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examination Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I. ☒ Basis of the opinion
- II. ☐ Priority
- III. ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV. ☐ Lack of unity of invention
- V. ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI. ☐ Certain documents cited
- VII. ☐ Certain defects in the international application
- VIII. ☐ Certain observations on the international application

Date of submission of the demand 23.10.2003	Date of completion of this report 19 July 2004 (19.07.2004)
Name and mailing address of the IPEA/AT Austrian Patent Office Dresdner Straße 87 A-1200 Vienna Facsimile No. 1/53424/200	Authorized officer SLABY S. Telephone No. 1/53424/348

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International application No.
PCT/IN 2003/000156

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____.
- ☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____.
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____.
- ☐ the claims, Nos. _____.
- ☐ the drawings, sheets/fig _____.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as „originally filed“ and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement			
1. Statement Novelty (N)	Claims	8-21	YES
	Claims	1-7	NO
Inventive step (IS)	Claims	8-21	YES
	Claims	1-7	NO
Industrial applicability (IA)	Claims	1-21	YES
	Claims	----	NO

Citations and explanations (Rule 70.7)

The following documents have been cited in the Search Report:

D1: WO 85/03707 A1
D2: WO 99/01450 A1
D3: WO 02/42290 A1

The present application relates to substantially pure desloratadine (claims 1-7) and methods for the preparation thereof (claims 8-21).

D1 and D2 describe the preparation of pure desloratadine. Though D1 and D2 do not disclose characterisation of the product with HPLC, as in the present case, desloratadine of D1 and D2 can be acknowledged as pure:

It is common general knowledge that any chemical compound obtained by a chemical reaction would normally contain impurities for various reasons and that it is not possible for thermodynamical reasons to obtain a compound, which is – in the strict sense – completely pure. It is, therefore, common practice for a person skilled in the art of preparative chemistry to purify a compound obtained in a particular chemical manufacturing process according to the prevailing needs and requirements. Conventional methods for the purification of low molecular organic reaction products, which could normally be successfully applied in purification steps, are within the common general knowledge. It follows that a document disclosing a low molecular chemical compound and its manufacture make this compound available to the public in all grades of purity as desired by a person skilled in the art.

Additionally D2 discloses polymorphs of desloratadine which have a Purity of 100% (examples 2-4).

Therefore claims 1 – 7 cannot regarded as novel in the sense of Article 33 (2) PCT.

Since none of the cited documents D1-D3 discloses all essential and characteristic features of the present claims 7-21, the subject matter of these claims is regarded to meet the requirement of novelty (Article 33 (2) PCT) and though the subject matter of the

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International application No.
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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V (page 1)

present the present claims 7-21 cannot be regarded as obvious, inventive step is acknowledged (Article 33 (3) PCT).

Industrial applicability is given.